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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC.; CYTYC CORPORATION; and HOLOGIC LP,

Plaintiffs,

v.

SENORX, INC.,

Defendant.

No. C-08-00133 RMW

ORDER DENYING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION **(Redacted Version)**

[Docket No. 8]

[PUBLIC VERSION]

On January 8, 2008 plaintiffs Hologic, Inc., Cytyc Corporation and Hologic LP (collectively "Hologic") filed the instant action against defendant SenoRx, Inc. ("SenoRx"), alleging infringement of three Hologic patents: U.S. Patent Nos. 6,413,204 ("the '204 patent"), 6,482,142 ("the '142 patent") and 5,913,813 ("the '813 patent"). Hologic now seeks a preliminary injunction enjoining SenoRx from selling or offering to sell its Contura Multi-Lumen Balloon on the basis that the product infringes two of the claims of the patents-in-suit: claim 36 of the '204 patent and claim 1 of the '142 patent.[1] For the reasons set forth below, the court denies Hologic's motion.

[1] Hologic notes that it has alleged and will seek to prove at trial that SenoRx infringes additional claims of the patents-in-suit, but have elected to focus on two claims for purposes of the motion for preliminary injunction in order to streamline the issues.

I. BACKGROUND

The parties develop products for use in breast brachytherapy. Brachytherapy is a form of radiation therapy whereby a radioactive source is placed inside or near an area requiring treatment. For breast brachytherapy, breast tumors are removed via a lumpectomy procedure and a device for delivering radiation is placed in the tumor cavity. The goal of such a treatment is to more efficiently deliver radiation to any remaining cancerous tissue while minimizing damage to healthy tissue.

Hologic, owner of the patents-in-suit, manufactures and sells a balloon brachytherapy device known as the MammoSite Radiation Therapy System ("MammoSite"). Defendant SenoRx also markets a balloon brachytherapy device known as the Contura Multi-Lumen Balloon("Contura").

It is undisputed that the general structure and use of the MammoSite and Contura are the same. Both devices consist of a catheter body with an inflatable balloon on one end. Both devices are implanted into the lumpectomy cavity of a breast. Treatment of the breast involves inflating the balloon portion of the device with a contrast fluid to hold it in place and to conform the cavity to the shape of the balloon, and delivering a radiation source (a radioactive seed) through a lumen.

Hologic's MammoSite device has a single central lumen by which the radiation source may be placed within the balloon; the SenoRx Contura device accused of infringing has multiple lumens for placing radiation sources. Specifically, the Contura has five lumens, one straight central lumen and four surrounding curved lumens, into which radiation source wires can be inserted.[2] Hologic asserts that the Contura device infringes claim 36 of the '204 patent and claim 1 of the '142 patent and asks the court to issue a preliminary injunction to enjoin SenoRx from selling or offering to sell its Contura product.[3]

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[2] SenoRx asserts that the Contura can be either used as a "single-dwell" device such that only one radioactive source is inserted into one of the lumens or a "multi-dwell" device such that a radioactive source can be inserted into more than one of the lumens.

[3] Hologic indicated at the hearing on this matter that it did not intend to seek an injunction preventing SenoRx from manufacturing or conducting clinical studies on the Contura, only from conducting sales and marketing activities with respect to that device.

II. ANALYSIS

A party seeking a preliminary injunction must establish: (1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) a public interest favoring the injunction. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1374 (Fed. Cir. 2006). These factors can be established by demonstrating either "(1) a combination of probable success on the merits and the possibility of irreparable injury or (2) that serious questions are raised and the balance of hardships tips sharply in [the moving party's] favor." *Mikohn Gaming Corp. v. Acres Gaming, Inc.*, 165 F.3d 891, 895 (Fed. Cir. 1998) (citing *Dollar Rent A Car v. Travelers Indem. Co.*, 774 F.2d 1371, 1374-75 (9th Cir. 1985)).

To demonstrate likelihood of success, a patentee must present proof of the accused product's infringement of a "valid and enforceable patent." *Pfizer, Inc. v. Teva Pharmaceuticals, USA, Inc.*, 429 F.3d 1364, 1372 (Fed. Cir. 2005). "In resisting a preliminary injunction, . . . one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself." *Abbott Labs. v. Andrx Pharmaceuticals, Inc.*, 452 F.3d 1331, 1335 (Fed. Cir. 2006).

B. Claim 36 of the '204 Patent

Hologic asserts that the Contura infringes claim 36 of the '204 patent which reads:

> An interstitial brachytherapy apparatus for delivering radioactive emissions to an internal body location comprising:
>
> (a) a catheter body member having a proximal end and distal end;
>
> (b) an inner spatial volume disposed proximate to the distal end of the catheter body member;
>
> (c) an outer spatial volume defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume; and
>
> (d) a radiation source disposed in the inner spatial volume;
>
> wherein the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose for delivering therapeutic effects to a target tissue, the target tissue being defined between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface, the apparatus providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface.

SenoRx argues that the Contura device does not infringe and, further, that the broad construction claimed by Hologic renders the '204 patent invalid as anticipated.

1. Claim Construction

Determining the likelihood of patent infringement on a preliminary injunction motion requires two steps: 1) construction of the relevant claims; and 2) comparison of the construed claims to the accused product(s). *Pfizer*, 429 F.3d at 1372. The court previously addressed claim construction of the '204 patent claims in a prior declaratory relief action involving plaintiff Cytyc Corp., *Xoft, Inc. v. Cytyc Corp.*, Case No. 05-05312 RMW ("the *Xoft* action"). The parties have agreed that the claim construction in that case is controlling for the current motion.

The relevant claim terms or phrases the court construed are as follows:

Claim Term	Construction
"interstitial"	Involving a surgically-created cavity in a body.
"brachytherapy"	Radiation therapy delivered by a spatically-confined radioactive material inserted in tot eh body at or near the tumor or other proliferative tissue disease site.
"interstitial brachytheraphy"	(no construction necessary)
"inner spatial volume"	A region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide sphere.
"outer spatial volume"	A region of space defined by an expandable surface element and surrounding an inner "expandable surface element" (no construction necessary)
"radiation source"	Radionuclide
"the inner and outer spatial volumes are configured to provide a minimum dose"	(no construction necessary)
"a minimum distance outward from the outer spatial volume expandable surface"	(no construction necessary)
"a controlled dose"	(no separate construction necessary)
"to reduce or prevent necrosis in healthy tissue proximate to the expandable surface"	(no separate construction necessary)

"providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface"	Controlling the ratio of the dose at the expandable surface of the outer spatial volume to the prescribed dose at the depth of interest in the target tissue so that the dose at the expandable surface is not so high that it lethally damages cells in healthy tissue in contact with the expandable surface.

Xoft Claim Construction Order at 28-29.

2. Infringement

Hologic contends that the Contura is a device that literally satisfies every limitation of claim 36 of the '204 patent. SenoRx's primary argument for non-infringement of the '204 patent is that the Contura does not infringe because it does not have an "inner spatial volume."

As required by claim 36, the Contura device is an "interstitial brachytherapy apparatus for delivering radioactive emissions to an internal body location." It is undisputed that the Contura has "(a) a catheter body member having a proximal end and a distal end." It also has "(b) an outer spatial volume defined by an expandable surface element disposed proximate to the distal end of the body member . . ." in the form of an inflatable spherical balloon at the distal end of the catheter that is implanted in the tumor cavity.

The catheter body of the Contura has treatment lumen as well as lumens for inflation and vacuum that run from the proximal end to the distal end. The inflation lumens have ports on the proximal end for inflation of the balloon that is at the distal end of the catheter. The treatment lumens are those into which the radiation source wires are placed within the balloon at the distal end. Hologic asserts that "[e]ach of the five treatment lumens . . . constitutes a separate inner spatial volume proximate to the distal end of the Contura MLB [or a]lternatively, the five treatment lumens and the area within the balloon between and surrounded by those lumens together define one inner spatial volume." Plfs' Br. at 14.[4] The treatment lumens are surrounded by the inflatable balloon, and thus according to Hologic, the Contura's inflatable balloon is "(c) an outer spatial volume defined by

[4] In its reply brief and at oral argument, Hologic also advanced the theory that the radionuclide itself could be considered the inner spatial volume. Because, as pointed out at the hearing, SenoRx has not had the opportunity to respond to this argument, the court does not consider this theory of infringement.

an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume." Because the treatment lumen is meant to contain the radiation source, the Contura also has "(d) a radiation source disposed in the inner spatial volume." Finally, Hologic argues that the Contura meets the final limitation regarding dosage,[5] because treatment using the Contura requires the parameters of the balloon size and location to be adjusted to conform the surgical cavity to the shape of the balloon and the radiation source wires are inserted into selected treatment lumens for prescribed lengths of time to control the radiation dose and prevent damage to healthy tissue.

SenoRx does not dispute that the Contura is a balloon brachytherapy device, but contends that its treatment lumens are not an "inner spatial volume" under the court's construction. As set forth above, the court construed "inner spatial volume" to be "a region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide sphere."

First, SenoRx argues that the Contura lumens cannot be an "inner spatial volume" because the '204 patent makes it clear that lumens and the "inner spatial volume" are different things. SenoRx points to the "balloon-within-a-balloon" embodiment, illustrated in Figure 1, in which the inner spatial volume is labeled **30** with a film wall **32**, while two lumens are separately labeled **14** and **16**. SenoRx contends that these depictions of lumens separate from the inner spatial volume clearly demonstrate that the lumens in the Contura device cannot be the inner spatial volume. As Hologic points out, however, the lumens depicted at 14 and 16 are inflation lumens, as is evident from the written description:

> A surgical instrument 10 . . . is illustrated in Fig. 1. Surgical instrument 10 includes a tubular body member 12 having first and second lumens 14 and 16 (FIG. 2) extending from proximal ports 18 and 20 in a molded plastic hub 22 *to inflation ports 24 and 26 formed through the side wall of the tube 12 and intersecting with the lumens 14 and 16, respectively.*

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[5] The final limitation reads: "wherein the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose for delivering therapeutic effects to a target tissue, the target tissue being defined between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface, the apparatus providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface"

'204 patent at 3:49-56 (emphasis added). These lumens are tubes through which air or fluid are pumped to inflate the balloons of the described device. As Hologic argues, the Contura itself appears to also have lumens that are used solely for inflation of the balloon at the distal end of the device. The court does not find persuasive SenoRx's argument that lumens are depicted separately from the inner spatial volume in the balloon-with-a-balloon embodiment and thus a treatment lumen may be considered an inner spatial volume.

SenoRx also points to the solid radionuclide embodiment set forth in the written description. In that embodiment, the inner spatial volume is a "solid spherical radiation emitting material **44**" rather than being defined by a polymeric film wall as in the balloon-with-a-balloon embodiment. SenoRx argues that the '204 patent distinguishes between the lumen and the inner spatial volume by describing that "solid radiation emitting material 44 can be inserted through catheter 12 on a wire 46." '204 patent at 4:46-48. The court does not find that this description clearly distinguishes the lumen from the inner spatial volume, and it thus rejects SenoRx's argument that the '204 patent necessarily sets forth the lumen and the inner spatial volume as distinct from one another.

Second, SenoRx argues that pursuant to the claim construction, "a region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide sphere," the inner spatial volume must be completely surrounded by the outer spatial volume. SenoRx points out that the lumens in the Contura device protrude into the catheter shaft and thus cannot be an inner spatial volume because they are not completely surrounded by the outer spatial volume. Hologic asserts that it is not necessary for the lumen to be entirely surrounded by the outer spatial volume and that the radionuclide within the polymeric film of the lumen meets the limitation. Hologic's interpretation is persuasive. Otherwise, the court's construction would exclude embodiments wherein the portion of the device holding the radioactive material in the inner spatial volume was in contact with the outer spatial volume. This would impermissibly exclude the preferred embodiment from the claims. *See* '204 patent at 3:57-65 and Figs 1 & 3 ("The interior of the inner volume 30 is in fluid communication with the inflation port 26."). Oatey Co. v. IPS Corp., 514 F.3d 1271, 1276-77 (Fed. Cir. 2008) ("We normally do not interpret claim terms in a way that excludes embodiments disclosed in the specification. . . .

However, we have interpreted claims to exclude embodiments of the patented invention where those embodiments are clearly disclaimed in the specification."); *Lava Trading, Inc. v. Sonic Trading Mgmt., LLC*, 445 F.3d 1348, 1353-55 (Fed. Cir. 2006) (rejecting claim construction that "excluded embodiments disclosed in the specification" including embodiments in the drawings); *see also Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (interpretation of patent so that preferred embodiment falls outside of patent claim is rarely, if ever, correct and would require highly persuasive evidentiary support).

The court therefore finds SenoRx's argument that the lumens of the Contura cannot be the inner spatial volume to be unpersuasive. Accordingly, Hologic has established a high likelihood of success on the merits by showing that the Contura infringes claim 36 of the '204 patent.

3. Invalidity

An accused infringer may successfully challenge a motion for preliminary injunction by raising a "substantial question" concerning validity, enforceability, or infringement. *Abbott Labs.*, 452 F.3d at 1335 n.2. However, no "substantial question" is raised if the patent holder can show that the proffered defense "lacks substantial merit." *Id.* Here, SenoRx argues that under plaintiffs' urged interpretation of the court's claim construction, the '204 patent is anticipated by an article from 1991 titled "A New Technique of Bracytherapy for Malignant Gliomas with Caesium-137: A New Method Utilizing a Remote Afterloading System" by Ashpole, et al. ("the Ashpole article"). Decl. of Aaron Maurer ("Maurer Decl."), Ex. 5.

"When moving for the extraordinary relief of a preliminary injunction, a patentee need not establish the validity of a patent beyond question. [citation] The patentee must, however, present a clear case supporting the validity of the patent in suit." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1359 (Fed. Cir. 2001) (citing *Atlas Powder Co. v. Ireco Chems.*, 773 F.2d, 1230, 1233 (Fed. Cir. 1985)); *see also Abbott Labs.*, 452 F.3d at 1335 ("The showing of a substantial

question as to invalidity . . . requires less proof than the clear and convincing showing necessary to establish invalidity itself.").[6]

The Ashpole article discloses an interstitial balloon brachytherapy device for use in brain tumor cavity treatment. *See* Decl. Colin Orton Supp. Def's Opp'n ¶¶ 12-14. SenoRx argues that the Ashpole article discloses every limitation of the '204 patent. Hologic contends, however, that the Ashpole article does not disclose either expressly or inherently, the final limitation of the '204 patent:

> wherein the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose for delivering therapeutic effects to a target tissue, the target tissue being defined between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface, the apparatus providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface

In particular, Hologic points to three defects in the Ashpole article. First, the Ashpole article discloses a radiation dose at the surface of the balloon that is higher than the tolerance of normal brain tissue. Hologic argues that this demonstrates that the Ashpole article does not teach an apparatus "providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface." Second, Hologic contends that the Ashpole article purports to solve the problem of necrosis in brain tissue from radiation by providing a removable balloon applicator – it does not teach configuring inner and outer spatial volumes such that the target tissue to be irradiated is "defined between the outer spatial volume expandable surface and a minimum distance outward from the spatial volume expandable surface." Third, Hologic argues that the Ashpole article teaches away from configuring the outer spatial volume as claimed in the '204 patent because the brain would be unable to tolerate the inflation of the balloon to conform the surgical cavity to the desired shape of the balloon. Brain tissue is sensitive to compression and deformation, making the technique of configuring the outer spatial volume unsuitable for use in brain treatment.

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[6] The burden of establishing invalidity is "especially difficult" when an accused infringer attempts to rely on prior art that was before the patent examiner during prosecution. *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1348 (Fed. Cir. 2004) (citing *Al- Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1323 (Fed. Cir. 1999)). Here, the Ashpole article was considered by the patent examiner during prosecution of the '204 patent. Nevertheless, the court finds that SenoRx has made a substantial showing of invalidity.

The court does not find plaintiffs' first argument to be persuasive. The court construed the relevant part of the claim as follows: "Controlling the ratio of the dose at the expandable surface of the outer spatial volume to the prescribed dose at the depth of interest in the target tissue so that the dose at the expandable surface is not so high that it lethally damages cells in healthy tissue in contact with the expandable surface." That the Ashpole article discloses that the outer surface of the balloon may deliver a higher radiation level than normally tolerated by normal brain tissue does not necessarily mean that the dose is not controlled so as not to lethally damage cells in healthy tissue in contact with the expandable surface. As to the second argument, the Ashpole article does disclose configuring the inner and outer spatial volumes to provide a minimum prescribed absorbed dose for delivering therapeutic effects to target tissue at the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface. The Ashpole article specifically states that "[t]he dose at the surface of the balloon depends on the number and arrangement of sources as well as the balloon diameter . . ." It further teaches that "the configuration of the balloon plays a key role in producing an acceptable dose distribution. The inverse square relationship between absorbed dose and distance from the source results in the larger the balloon diameter the greater the relative dose at prescribed distance from the balloon's surface." Ashpole article at 336; *see also* Orton Decl. ¶¶ 19-22.

Hologic's third argument that Ashpole teaches away from configuring the outer spatial volume at first glance appears to have some merit, but on closer inspection lacks support. Tumor cavities may be irregular in shape and, according to Hologic, the claimed invention requires the expandable balloon element to inflate to conform the tumor cavity to the shape of the balloon to achieve proper treatment. Specifically, Hologic argues that the language "providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface" requires the claimed invention be able to expand its outer spatial volume to conform the tumor cavity to the shape of the balloon. To the extent that this is a correct interpretation of the claim language, the Ashpole reference would teach away from claim 36 (according to Hologic) because compressing the surrounding brain tissue in this fashion would result in pressure that would be lethal to the tissue, because brain tissue is far more sensitive to pressure

than breast tissue. Therefore, Hologic argues, the balloon in the Ashpole article can only be inflated until it first contacts tissue.

The court does not, however, read into the language cited by Hologic the requirement that the outer balloon expand to conform the cavity to the shape of the balloon. Hologic points to the following language in the specification in support of its interpretation that "providing a controlled dose" requires the outer balloon to conform the tumor cavity to the shape of the balloon:

> Where the apparatus of the invention is deployed in soft tissue, it may also be important for the surface 36 of out spatial volume 34 to be sufficiently firm so as to force the target tissue to take on the shape of the surface 36 so that the desired relationship between the isodose profiles and the target tissue is achieved.

'204 patent at 5:36-41. While this language supports the idea that conforming the target tissue to the shape of the balloon "may be important" to achieving the appropriate dosage for the target tissue, it does not support the interpretation that "providing a controlled dose" necessarily entails making the tissue so conform. This is particularly true when the court considers claim 4 of the '204 patent. Claim 4 is a dependent claim which specifically claims "the apparatus of claim 3, wherein the expandable surface element is adapted to contact tissue surrounding a resected cavity and adapted to conform the tissue to the desired shape of the expandable surface element." This claim depends, through claim 3 on claim 2, which in turn depends on claim 1. Claim 1 sets forth the basic elements of "[a]n interstitial brachytherapy apparatus for delivering radioactive emissions to an internal body location," while claim 2 specifies how the apparatus provides a "controlled dose" of radiation at the outer spatial volume of the apparatus.[7] Claim 4 further claims the "expandable surface element" that is "adapted to conform the tissue to the desired shape of the expandable surface element."

Like claim 2, claim 36 claims the basic elements of the claimed "interstitial brachytherapy apparatus" as well as how the apparatus delivers the "controlled dose at the outer spatial volume expandable surface." Tellingly, claim 36 does not further claim the expandable surface element

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[7] Claim 2 of the '204 reads in its entirety:

> The apparatus of claim 1, wherein the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose for delivering therapeutic effects to a target tissue, the target tissue being defined between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface, the apparatus providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface.

adapted to conform the tissue to the shape of the expandable surface element. This suggests that the "controlled dose" referred to in claim 36 does not require the outer spatial volume to conform the tissue of the tumor cavity to the shape of the outer spatial volume in order to deliver the controlled dose.

Even if Hologic's interpretation is assumed and use of the "controlled dose" language requires the balloon to expand to conform the tumor cavity to the shape of the balloon, there is evidence that the Ashpole article does not teach away from such an application. Figure 3 of the Ashpole article shows an inflatable device in a tumor cavity located in the brain. Ashpole article at 335. That figure appears to depict the exterior balloon surface in contact with the entire tumor cavity surface, which, assuming an irregular tumor cavity, may indicate that the device was inflated to conform the tumor cavity to the shape of the balloon.

Although SenoRx has certainly not proven that the '204 patent is invalid based on the Ashpole article by clear and convincing evidence, the court concludes that SenoRx has shown a substantial question as to invalidity of the '204 patent. *Abbott Labs.*, 452 F.3d at 1335. Accordingly, the court finds that Hologic has not shown a substantial likelihood of success with respect to its allegation that the Contura infringes the '204 patent.

B. Claim 1 of the '142 Patent

Hologic also asserts that the Contura infringes claim 1 of the '142 patent which reads:

> An interstitial brachytherapy apparatus for treating target tissue surrounding a surgical extraction comprising:
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> an expandable outer surface defining a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated;
>
> a radiation source disposed completely within the expandable outer surface and located so as to be spaced apart from the apparatus volume, the radiation source further being asymmetrically located and arranged within the expandable surface to provide predetermined asymmetric isodose curves with respect to the apparatus volume.

SenoRx argues that the Contura device does not infringe and, further, that a prior art patent renders this claim invalid as anticipated or obvious.

1. Claim Construction

The claims of the '142 patent were not at issue in the *Xoft* action. In its opening brief, Hologic urges the court to adopt its construction from the *Xoft* action with respect to the claim terms that are the same as those in the '813 and '204 patents. It also asserts that the meanings of the unconstrued claim terms in the '142 patents are clear and that they should be given their ordinary and customary meaning. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-14 (Fed Cir. 2005) (en banc).

SenoRx, on the other hand, urges the court to construe the following claim terms: "three-dimensional apparatus volume" and "disposed completely within." Because they are so intertwined with its non-infringement contentions, SenoRx's arguments regarding claim construction will be addressed in the discussion of infringement.

2. Infringement

There is no dispute between the parties that the Contura is "an interstitial brachytherapy apparatus for treating target tissue surrounding a surgical extraction." There is further no dispute that the Contura's inflatable balloon operates as "an expandable outer surface defining a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated."

Claim 1 requires "a radiation source disposed completely within the expandable outer surface." Further, to infringe the patent, the radiation source must be "located so as to be spaced apart from the apparatus volume" and further be "asymmetrically located and arranged within the expandable surface to provide predetermined asymmetric isodose curves with respect to the apparatus volume."

As set forth above, the radiation sources for the Contura are radioactive wires that are inserted into the central and curved treatment lumens. Hologic contends that the central and curved treatment lumens of the Contura do not touch the interior surface of the expandable surface of the balloon of the Contura device and therefore are spaced apart from the apparatus volume. SenoRx, on the other hand, urging a construction of "volume" as "region of space," argues that it is impossible for the radiation source to be spaced apart from the "apparatus volume."

Hologic also argues that the radiation sources are within the boundary of the balloon and therefore the Contura has a radiation source "disposed completely within the expandable outer surface" because the radiation sources in the lumens of the Contura device are enclosed by the inflatable balloon. SenoRx, however, urges a different meaning for "disposed completely within the expandable outer surface," contending that the term means that the radiation source cannot be removable from the device. Because the radiation sources for the Contura are designed to be inserted only after the device is implanted and are removed from preprogrammed positions after predetermined periods of time, SenoRx argues that the radiation sources in the Contura are not "disposed completely within the expandable outer surface."

a. "Three-Dimensional Apparatus Volume"

SenoRx argues that "three-dimensional apparatus volume" should be construed as the "three-dimensional region of space within the expandable outer surface." Hologic does not offer an alternative construction, but it does strenuously contest the construction proposed by SenoRx.

SenoRx asks for this construction because claim 1 of the '142 patent requires that the radiation source be "located so as to be spaced apart from the apparatus volume." Because the radiation source cannot be spaced apart from the "three-dimensional region of space within the expandable outer surface," SenoRx contends that this claim must be invalid as indefinite.

In support its argument that "three-dimensional apparatus volume" should be defined by reference to the "region of space within the expandable outer surface," SenoRx refers to this court's construction of "inner spatial volume" and "outer spatial volume" for purposes of the '204 patent in the *Xoft* action wherein the court construed "volume" to be a "region of space."[8] SenoRx further points out that the court noted the difference between a "volume" and the "boundary of a volume" in rejecting Xoft's proposed construction that "inner spatial volume" be the "inner balloon in two-balloon device or spherical solid radionuclide in one-balloon device" stating "that Xoft's construction conflates the boundary of the volume with the volume itself." Xoft Claim Construction Order at 5.

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[8] The court construed "outer spatial volume" as "*a region of space* defined by an expandable surface element and surrounding an inner spatial volume" and likewise construed "inner spatial volume" as "*a region of space* surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide sphere."

This construction was consistent with construction advanced and the arguments made by Cytyc (here, Hologic):

> More fundamentally, Xoft confuses the tangible structure that defines the inner spatial volume with the volume itself. The specification provides that the inner spatial volume 30 "may be defined by a generally spherical polymeric film." The film defines the boundary of the volume but the volume is the region of space within that boundary.

Maurer Decl., Ex. 8 (Plf. Cl. Constr. Br.) at 9.

SenoRx additionally argues that claim 1 itself defines volume as a region of space. Claim 1 recites "a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated." SenoRx contends that a "volume" must be "region of space" because only a volume can be "configured to fill an interstitial void" created by removal of the tumor. Further, the claim itself appears to distinguish between "volume" and "surface," requiring "a radiation source disposed *completely within the expandable outer surface* and located so as to be *spaced apart from the apparatus volume*." SenoRx asserts that the court is precluded from correcting such an error in the claim by looking back to the written description, citing in support *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357 (Fed. Cir. 1999).

While there is some appeal to the argument that the claim itself distinguishes between volume and surface, and to the argument that the court should consistently construe "volume" to be "region of space" with the '813 and '204 patents, the court notes that claim 1 provides that the same "three-dimensional apparatus volume" that SenoRx asserts can only refer to a region of space also "define[s] an inner boundary of the target tissue being treated." This use of the limitation supports Hologic's contention that the inventors intended "volume" to also refer to the surface of the apparatus. Reading this portion of the claim, the "three-dimensional apparatus volume" appears to refer to the surface of the apparatus, as it is the surface of the balloon that is contact the tissue to be treated and defines the inner margin of tissue to be irradiated. *See also* '142 patent at 4:27-30 (the outer spatial volume is "defined by an outer polymeric film barrier **32** that is appropriately spaced from the radioactive source").

Because the claim itself seems to be amenable to the interpretation that volume is used interchangeably with surface, the court does not read *Process Control* as prohibiting looking to the written description for support of the interpretation urged by Hologic. The *Process Control* court held that "[t]he district court's attempt to use the written description to circumvent the plain language of the claim and the clear definition of the disputed claim language found therein was inappropriate." 190 F.3d at 1357. The court found that the disputed claim was susceptible to only one reasonable construction. *Id.* Here, by contrast, the language is much more ambiguous and the court cannot say that "volume" is so clearly defined that it would not be understood to refer to the surface so as to put one of reasonable skill in the art on notice of what was being claimed.

The claim is not the model of clarity. The court is troubled by Hologic's seeming reversal of its position from the *Xoft* action, now arguing that volume is the same as surface when it previously argued that volume and surface could by no means be the same. It is also of concern that Hologic does not to be able to propose an alternate construction of this limitation – the court supposes the reason is that it is difficult to harmonize a volume that fills a cavity with a volume that acts as a surface from which the radiation source that is supposed to be within the volume is to be spaced apart. Nevertheless, a common sense reading seems to indicate that one of skill in the art could understand the claim to mean that the radiation source must be inside and spaced apart from the surface of the expandable outer surface. Further, to construe the "three-dimensional apparatus volume" as SenoRx urges would result in both excluding all of the preferred embodiments and invalidating claim 1 of the '142 patent, which the court is aware must, if possible, be avoided. SenoRx has not presented highly persuasive evidentiary support that the inventors intended to exclude all preferred embodiments, *Vitronics*, 90 F.3d at 1583, while it does raise some significant question regarding whether the claim drafter made a mistake that may be fatal to the claim. The court finds it to be a very close call as to whether SenoRx has made a substantial showing that the claim is vulnerable to an assertion of invalidity. But, as discussed more fully below in Section D, even assuming the patent is valid and infringed based upon Hologic's preliminary showing, the court would be reluctant to grant a preliminary injunction.

a. Disposed Completely Within

SenoRx argues that the Contura does not use a radiation source "disposed completely within" the balloon and instead uses a radiation source that is "replaceably disposable within" the balloon. It claims that having a radiation source that is "replaceably disposable within" was a limitation that was originally included in claim 1 but was disclaimed during prosecution in order to avoid prior art. Hologic acknowledges that the claim was amended to remove "replaceably disposable within" and insert "disposed completely within" but argues that the two limitations refer to distinct and independent concepts. It contends that "replaceably disposable within" pertains to whether the radiation source can be replaced, while "disposed completely within" relates to how much of the radiation source is placed entirely within the outer balloon. Hologic further characterize SenoRx's argument as attempting to rewrite the limitation from "a radiation source disposed completely within the expandable outer surface" to "a radiation source [irreplaceably] disposed completely within the expandable outer surface."

SenoRx supports it contention that "disposed completely within" means that the radiation source cannot be removed by pointing to two embodiments of the invention set forth in the specification of the '142 patent. The specification sets forth that:

> The radioactive source 24 can either be preloaded into the catheter at the time of manufacture, or loaded into the device after it has been implanted into the space formerly occupied by the excised tumor. If loaded after implantation, the solid radiation emitting material 36 can be inserted through lumen 14 on wire 34 for example using an afterloader (not shown).

'142 patent at 5:5-11. SenoRx contends that claim 1 as originally submitted as claiming a "radiation source replaceably disposable within the expandable outer surface, *see* Maurer Decl., Ex. 9 at SRX-HOL177, was rejected as anticipated by U.S. Patent No. 6,036,631, "Device and Method for Intracavitary Cancer Treatment" by McGrath, et al. *See* Maurer Decl., Ex. 10 at 2. The examiner stated that McGrath, et al., "discloses a device for treating tissue having an expandable outer surface and a radiation source disposed within the expandable surface having a plurality of solid radiation sources." *Id.* (citing, in particular, Fig. 2). In response to that office action, claim 1 was amended to replace "replaceably disposable within" with "disposed completely within." Maurer Decl., Ex. 12 at 2. While SenoRx characterizes the amendment as intending to narrow the claim to only the

embodiment wherein the radioactive source is preloaded into the catheter at the time of manufacture (and is therefore not removable), the explanation of the amendment appears to contradict this characterization. The explanation for the amendment provides:

> The device of McGrath is not configured for use interstitially, it is configured for use interluminally, with balloons provided only to hold the catheter within a lumen, or to dilate the lumen. Accordingly, the radiation source in McGrath is not located completely within any of the disclosed balloons, nor is it located and arranged to provide an asymmetric dose at an apparatus volume that conforms to an interstitial void. Rather, McGrath provides an x-ray tube 48 that slides within a catheter, or a plurality of radiation-emitting seeds 52 "essentially forming a linear source."

Id. at 7. SenoRx argues that while part of the explanation, "the radiation source in McGrath is not located completely within any of the disclosed balloons" addresses the fact the radiation source in McGrath is disclosed as a linear radiation source that extends past the balloon depicted, another part, "[r]ather, McGrath provides an x-ray tube 48 that slides within a catheter," is meant to address the fact that the McGrath radiation source is removable. According to SenoRx, this second portion of the explanation is intended to distinguish the claimed invention from McGrath, and, therefore, the amended language only claims a non-replaceable radiation source (the preferred embodiment in which the radiation source is manufactured as part of the device) and not McGrath's slideable, removable radiation source.

This argument is not convincing. The explanation provided for the amendment of claim 1 does not clearly indicate any intent to restrict the claim to only radiation sources that are not removable from the device. The reference to the "x-ray tube 48 that slides within a catheter" is immediately followed by "or a plurality of radiation-emitting seeds 52 'essentially forming a linear source.'" This indicates that the applicant was continuing to describe the shape of the radiation source as expanding outside the boundary of the balloon rather than that the applicant intended to disclaim replaceable sources.

By contrast, the explanation given to the examiner does indicate that the inventors considered a distinguishing feature of their invention that the radiation source in their invention was located completely within the disclosed balloon, while the radiation source in McGrath was not, with the x-ray tube or radiation-emitting seeds in McGrath instead forming a linear source. The removal of the "replaceably disposable within" limitation from the claim during prosecution was not meant to limit

the claim to a radiation source that cannot be inserted into and removed from the device. Changing "replaceably disposable within" to "disposed completely within" was meant to limit the claim such that the radiation source is completely surrounded by the expandable outer surface; it was not meant to limit the claim with regard to whether the radiation source was removable.

There is no dispute that the radiation source for the Contura is not preloaded in the balloon but is delivered by afterloader at the time of treatment. Even assuming that this feature meets the intended definition of the "replacably disposable within" limitation that was removed from claim 1 during prosecution, nothing in claim 1 precludes such a radiation source from meeting the limitation of being "disposed completely within," or surrounded by, the expandable outer surface.

3. Invalidity

SenoRx asserts that claim 1 of the '142 patent is invalid as anticipated by or obvious over U.S. Patent No. 5,931,774, to Williams ("the 774 patent"). Hologic, on the other hand, argues that the '774 patent does not disclose a radiation source "located and arranged . . . to provide predetermined asymmetric isodose curves" as required by claim 1.

The parties dispute initially whether the '774 patent discloses any asymmetry. SenoRx points to Figure 3 of the '774 patent, which depicts a "schematic cross-sectional view of a double-balloon embodiment of a treatment device of the invention." '774 patent at 3:1-2. The drawing appears to depict an inner balloon 40 filled with radioactive fluid 42 that is not centered in the outer balloon 24. SenoRx argues that this demonstrates that the '775 discloses an asymmetric configuration. Hologic contends that Figure 3 cannot be the basis for anticipation because "patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue." *Nystrom v. TREX Co., Inc.*, 424 F.3d 1136, 1149 (Fed. Cir. 2005).

SenoRx does not dispute that the specification says nothing about arranging the radioactive source in an asymmetric fashion, rather, it argues that *Nystrom* only applies to circumstances in which a determination is made as to specific proportions and numbers, for example, where a patent drawing is analyzed to establish particular quantitative values where the specification does not otherwise discuss those values. The court disagrees that *Nystrom* is so narrowly limited. *Nystrom*

relied upon *Hockerson-Halberstadt, Inc. v. Avia Group Intern., Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000), in which the Federal Circuit determined that the purportedly anticipating reference was "devoid of any indication that the proportions of the groove and fins are drawn to scale" and thus the anticipation argument hinged "on an inference drawn from certain figures about the quantitative relationship between the respective widths of the groove and fins." *Id.* at 956. It stated, "Under our precedent, however, it is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue." *Id.* (citing *In re Wright*, 569 F.2d 1124, 1127 (C.C.P.A. 1977) ("Absent any written description in the specification of quantitative values, arguments based on measurement of a drawing are of little value.")). Here, likewise, there is no indication that the drawings are intended to show arrangement in an asymmetric fashion and the court finds the drawing may be configured merely to provide a clear picture of the components.

Even assuming Figure 3 could be considered to disclose an asymmetric configuration, the '774 reference still fails to disclose how an asymmetric isodose curve would have been calculated with regard to the device. On this point, SenoRx's expert, Dr. Colin Orton, opines only that "[a] person of ordinary skill in the art would understand that, before the device . . . was used for therapeutic treatment of a patient via insertion of a radioactive fluid in the inner balloon, a radiation oncologist or radiation physicist necessarily would have calculated the dose (and isodose profile) that would be generated by the device." Orton Decl. ¶ 50. The court finds this conclusory statement to be insufficient to demonstrate that the '774 patent meets the disputed limitation for purposes of anticipation. While SenoRx may eventually be able to demonstrate that the '774 patent is invalidating prior art, at this point, the court concludes that defendant has failed to show a substantial question as to invalidity of the '142 patent as anticipated or rendered obvious by the '774 patent. *Abbott Labs.*, 452 F.3d at 1335.

D. Preliminary Injunction

1. Likelihood of Success on the Merits

As set forth above, the court has found that Hologic has not established a likelihood of success on the merits as to the '204 patent. Although Hologic has demonstrated that the Contura

likely infringes claim 36 of the '204 patent, because SenoRx has presented a substantial question regarding that patent's invalidity as anticipated by the Ashpole article, Hologic has not established that it has a likelihood of success on its infringement claim with respect to the '204 patent.

Hologic has also demonstrated a likelihood of success as to its claim that the Contura likely infringes the '142 patent. There remains a question whether claim 1 of the '142 patent is invalid as indefinite, given the ambiguity regarding the "volume" versus "surface" distinction set forth above with regard to the limitation requiring the radiation source to be "located so as to be spaced apart from the apparatus volume" defined by the outer surface. SenoRx has not otherwise presented a substantial question regarding the invalidity of the '142 patent. But even if the court had found unequivocably that the evidence preliminarily showed infringement of a valid patent, the court would not grant a preliminary injunction.

2. Irreparable Harm

A plaintiff must show that irreparable harm will result if the injunction does not issue. In patent infringement suits pre-dating *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006), "a strong showing of likelihood of success on the merits coupled with continuing infringement raise[d] a presumption of irreparable harm to the patentee." *Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1556 (Fed. Cir. 1994); *see Abbott Labs.*, 452 F.3d at 1347. The presumption of irreparable harm could be rebutted, for instance, by producing evidence that the patentee would not be harmed if the preliminary injunction does not issue. *Id.*

Following the Supreme Court's decision in *eBay*, there is a difference of opinion on whether movants for preliminary injunctions are entitled to a presumption of harm. In *eBay*, the Supreme Court overruled the Federal Circuit's "general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances." *Id.* at 392-93. Subsequent to the Court's decision, courts have split as to whether the presumption of irreparable harm applies in motions for preliminary injunctions. *Compare Novartis Pharmaceuticals Corp. v. Teva Pharmaceuticals USA, Inc.*, 2007 WL 2669338 at *13 (D.N.J. Sept. 6, 2007) ("This court relies upon eBay's broader holding that, on motions for injunctions, courts should not apply categorical rules and presumptions"); *Torspo Hockey Intern., Inc. v. Kor Hockey Ltd.*, 491 F. Supp. 2d 871, 881 (D.

Minn. 2007) ("Although *eBay* involved permanent rather than preliminary injunctions, the Court believes that *eBay*'s logic forbids courts to categorically presume irreparable harm in the preliminary-injunction context, even if a patentee has established that it will likely succeed on the merits."); *Sun Optics, Inc. v. FGX Int'l., Inc.*, 2007 WL 2228569 at *1 (D. Del. Aug. 2, 2007) (noting that allowing presumption of irreparable harm to attach on preliminary injunction application after showing of likelihood of success on merits appears inconsistent with *eBay*); *Chamberlain Group, Inc. v. Lear Corp.*, 2007 WL 1017751 at *5 (N.D. Ill. Mar. 30, 2007) (extending holding of *eBay* to preliminary injunctions) *with Christiana Industries v. Empire Electronics, Inc.*, 443 F. Supp. 2d 870, 884 (E.D. Mich. 2006) ("The *eBay* Court addressed the proper analysis for permanent injunctive relief. It held that courts err by categorically granting permanent injunctive relief on a showing of infringement and validity, without analyzing the traditional four factors for injunctive relief.").[9]

The Court emphasized that a decision to grant injunctive relief is discretionary and that it has, in the analogous copyright context, "consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically follows a determination that a copyright has been infringed." *eBay*, 547 U.S. at 392-93.[10] Applying a presumption of irreparable harm in the preliminary injunction context would appear to replace equitable considerations with a rule that an injunction, however preliminary, automatically follows a determination that a valid patent has likely been infringed. The court is doubtful that the Supreme Court intended for the presumption to survive for purposes of preliminary injunctions. Thus, it does not appear that presumption of irreparable harm should be extended to preliminary injunction applications involving patents.

Although it asserts that it is entitled to a presumption of irreparable harm, Hologic does not rely upon that presumption and sets forth five additional grounds: (1) Hologic believes that SenoRx's

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[9] The Federal Circuit has not yet addressed this issue. *See, e.g., Amado v. Microsoft Corp.*, 517 F.3d 1353, 1359 (Fed. Cir. 2008) ("Amado argues that the district court 'improperly concluded that eBay eliminated the presumption of irreparable harm that follows a judgment of validity and infringement.' We find it unnecessary to reach this argument, however, because regardless of whether there remains a rebuttable presumption of irreparable harm following *eBay*, the district court was within its discretion to find an absence of irreparable harm based on the evidence presented at trial.").

[10] A district court opinion in the Ninth Circuit has held that no presumption of irreparable harm results from a finding of liability in a copyright case following *eBay*. *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 518 F. Supp. 2d 1197, 1210-14 (C. D. Cal. 2007).

primary business strategy is to poach MammoSite customers by underpricing Hologic; (2) Hologic believes based on SenoRx's financial results that SenoRx may never be able to compensate for the damage SenoRx will cause during litigation; (3) SenoRx's market presence will decrease Hologic's market share, revenue and profits in the accelerated partial breast irradiation ("APBI") market; (4) its market presence will harm Hologic's reputation as an innovator; and (5) SenoRx is promoting unproven, off-label treatments of patients with the Contura, which may irretrievably damage the reputation of ABPI as a form of treatment for breast cancer.

a. Motion to Strike Portions of the Magnuson Declaration

As an initial matter, Hologic relies on the declaration of Glenn Magnuson in support of its contentions that it will suffer irreparable harm in the absence of a preliminary injunction enjoining infringement of the '142 patent. SenoRx has moved to strike portions of the Magnuson declaration based on N.D. Cal. Civil Local Rule 7-5(b) which provides, "An affidavit or declarations may contain only facts, must conform as much as possible to the requirements of FRCivP 56(e), and must avoid conclusions and argument. Any statement made upon information or belief must specify the basis therefor. An affidavit or declaration not in compliance with this rule may be stricken in whole or in part."

Specifically, SenoRx objects to and moves to strike the last two sentences of paragraph 8 (statements regarding whether MammoSite practices the patents-in-suit – outside scope of personal knowledge); the first sentence of paragraph 11 (same); the fourth sentence of paragraph 12 (statements regarding why doctors and patients may not use MammoSite – speculative); paragraph 16 (statements regarding defendant's reputation – speculative); the fifth and sixth sentences of paragraph 18 (statements regarding the ABPI market – speculative, unsupported and outside the scope of declarant's expertise); the second sentence of paragraph 19 (hearsay); paragraph 21 except the last sentence (hearsay); and the first, second and last sentences of paragraph 23 (statements regarding the ABPI market – speculative, unsupported and outside the scope of declarant's expertise). *See* Decl. Glenn Magnuson ("Magnuson Decl.").

SenoRx's arguments on reply notwithstanding, its objections are based on the admissibility of the objectionable portions of the declarations. SenoRx specifically complains that the challenged

statements do not comply with Federal Rule of Civil Procedure 56(e), which is referenced in L.R. 7-5(b). As Hologic notes and SenoRx acknowledges on reply, Rule 56(e) does not directly apply in the context of a preliminary injunction and a court "may give inadmissible evidence some very limited weight in consideration of a motion for preliminary injunction." *Arthur J. Gallagher & Co., Inc. v. Edgewood Partners Ins. Center*, 2008 WL 205274 n.3 (N.D. Cal. Jan 23, 2008) (White, J.); *see also Bracco v. Lackner*, 462 F.Supp. 436, 442 (N.D. Cal. 1978). Accordingly, the court declines to strike the challenged portions of the Magnuson declaration, except paragraph 8 and the first sentence of paragraph 11.

As to paragraph 8 and the first sentence of paragraph 11, the court agrees that whether the MammoSite device practices the patents-in-suit is well outside the expertise of Magnuson. Magnuson does not have legal training nor does his product marketing position appear to provide him with a basis for an opinion regarding whether Hologic's device practices the patents-in-suit. The court will strike paragraph 8 and the first sentence of paragraph 11, as this evidence appears to be completely without foundation.

Courts may give inadmissible evidence some weight in consideration of a motion for preliminary injunction "when to do so serves the purpose of preventing irreparable harm before trial." *Flynt Dist. Co., Inc. v. Harvey*, 734 F.2d 1389, 1394 (9th Cir. 1984). Magnuson is currently the Senior Director of Product Marketing for Cytyc's Breast Health Unit. Magnuson Decl. ¶ 3. The objectionable statements concern knowledge Magnuson would accumulate as part of his job responsibilities in marketing Cytyc's breast health-related products. The court thus finds that, except as to the stricken statements discussed above, Magnuson's opinions are entitled to some weight under the circumstances of a preliminary injunction motion. *See Arthur J. Gallagher*, 2008 WL 205274 n.3 (the court may give appropriate weight to inadmissible testimony based on its discretion "and upon consideration of the competence, personal knowledge and credibility of the affiants").

b. Hologic's Allegations of Irreparable Harm

It is undisputed that SenoRx is just now starting to commercialize its Contura product. Hologic asserts that SenoRx's entry into the ABPI market will inflict multiple harms upon Hologic. Hologic argues that it will suffer irreparable harm by SenoRx entering the market with its Contura

product in the form of (1) lost market share to the lower priced product; and (2) price erosion in an attempt to maintain its market share. Hologic asserts that the harm is immediate and irreparable as SenoRx is presently targeting its customers and undercutting its price point.

[redacted]

SenoRx states that the Contura and the MammoSite have the same price point: $2750. It asserts that it has [redacted]

The court finds that it does appear that SenoRx is targeting Hologic customers and has offered some discounts to Hologic customers. With regard to Hologic's contention that the Contura will harm the market, SenoRx asserts that Hologic's product has been available since 2002 and, it believes, Hologic has failed to penetrate the potential market for post-lumpectomy radiation treatment. Gearhart Decl. ¶ 14; Decl. Roy Weinstein ("Weinstein Decl.") ¶ 28. SenoRx states that it intends to increase the market with its Contura product, [redacted]

[redacted]

While the entry of SenoRx into the APBI market may very likely cause a decrease in Hologic's market share, revenue and profits, Hologic's harms can be compensated economically.[11] Although Hologic contends that SenoRx is losing millions every quarter, SenoRx has estimated its total assets [redacted]. Weinstein Decl. ¶ 30-32. SenoRx's Vice President of Sale and Marketing [redacted]. Gearhart Decl. ¶ 16. This does not indicate to the court that SenoRx will be judgment-proof should it prevail on the merits of its patent claims in this action.

Hologic also argues that SenoRx's marketing of the Contura is causing it grave reputational injury, damaging not only its goodwill, but also potentially damaging the perception of ABPI as a mode of treatment. It contends that SenoRx is untested and that adverse results using Contura could be attributed to the reputation of ABPI treatment or even to SenoRx. The accusation that SenoRx's use and testing may be attributed to Hologic or to the ABPI treatment modality as a whole appears to be pure speculation on Hologic's part. Overall, the court finds that Hologic has not established the requisite irreparable harm.

c. SenoRx's Rebuttal of Irreparable Harm

A period of delay prior to seeking a preliminary injunction in a patent infringement suit "may be so significant, in the district court's discretion, as to preclude a determination of irreparable

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[11] SenoRx also argues that the license granted to Xoft demonstrates that Hologic can be compensated with money damages. As the court recalls the *Xoft* case, the technology accused of infringing the patents in that suit was an electronic radiation source rather than a radionuclide, which required different shielding and did not require an afterloader. There is no evidence that Hologic would be similarly willing to accept money damages from a competitor whose solution, like the MammoSite, uses the radionuclide approach and seems to compete more directly.

harm." *Hybridtech, Inc. v. Abbott Labs.*, 849 F.2d 1446, 1457 (Fed. Cir. 1988). But "a showing of delay does not preclude, as a matter of law, a determination of irreparable harm," instead "a period of delay is but one circumstance that the district court must consider in the context of the totality of the circumstances." *Id.* Here, [redacted] The court finds that this argument has some merit particularly given the upcoming conference for which Hologic has expressed urgency with regard to obtaining the injunction. This factor also indicates that Hologic has not met its burden of demonstrating irreparable harm.

3. Public Interest[12]

SenoRx argues that because the Contura is capable of treating a larger range of women with breast cancer than the MammoSite, the public interest does not favor enjoining the Contura because it deprives women of the treatment options that are available using the Contura. Hologic, on the other hand, argues that the public interest favors preliminarily enjoining SenoRx's sales and marketing of the Contura, contending that the Contura is untested and that SenoRx itself acknowledges that the Contura is not as well proven as other solutions like MammoSite. It also contends that SenoRx is promoting the Contura for off-label use.

Much of this issue centers around the FDA-approved label for the Contura device. The FDA approved label for the Contura reads:

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[12] The court has found that Hologic has not met its burden of showing irreparable harm, thus, it need not address any other preliminary injunction factor. *Reebok Int'l*, 32 F.3d at 1556 ("Because . . . a movant must establish both a likelihood of success on the merits and irreparable harm . . . the district court may deny a preliminary injunction based on the movant's failure to establish either of these two crucial factors without making additional findings respecting the other factors."). Nevertheless, the court will continue its analysis to demonstrate that these additional factors support its decision not to issue a preliminary injunction in this case.

> The breast cavity must be imaged before implantation to insure the applicator will fit appropriately. Do not use if the cavity is too small or if a skin surface to balloon surface distance of less than 5 mm will result.

Altemus Reply Decl., Ex. JJ. Hologic argues that this label is substantially identical to MammoSite's and that Contura achieved FDA clearance under 510(k) by referencing the MammoSite as a predicate device, permitting it to receive approval without clinical testing. The MammoSite label reads as follows:

> Imaging should verify a minimum skin distance of 5 mm from the balloon surface to skin surface; however, a minimum distance of 7 mm from balloon surface to skin surface is recommended.

Based upon the similarities between the labels, Hologic contends that any use of the Contura for distances of less than 5mm is an off label use for which, both parties agree, SenoRx is prohibited from marketing the Contura device.

SenoRx acknowledges that the Contura has been used at distances between 5 and 7 mm and for distances under 5mm. *See, e.g.*, Amended Compl., Ex. G ("2mm Contura skin distance gets about the same dose as 8mm skin distance Mammosite"). It argues that such use is not "off-label" because the warning statement "do not use if . . . a skin surface to balloon surface distance of less than 5 mm will result" refers only to implantation, not to radiation delivery because the prior sentence refers to imaging the breast cavity before implantation. SenoRx's reading is hypertechnical. "Use" cannot reasonably be read to refer only to implantation. SenoRx next argues that the "promotion" of which it has been accused has not been promotion at all, rather testing and internal preparation for responding to inquiries regarding off-label use that doctors may ask. Off-label use by doctors is permitted as an "accepted and necessary corollary of the FDA's mission to regulate," *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). Hologic does not dispute SenoRx's contention that a manufacturer is permitted to respond to questions about off-label uses under 21 U.S.C. § 360aaa-6.[13] The evidence presented by Hologic thus far appears to consist of

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[13] 21 U.S.C. § 360aaa-6 reads in relevant part as follows:
(a) Unsolicited request

> Nothing in section 360aaa of this title shall be construed as prohibiting a manufacturer from disseminating information in response to an unsolicited request from a health care practitioner.

internal training materials and not for direct marketing to physicians and other customers. Hologic additionally contends that the off-label use of the Contura device at a distance of less than 5mm from the skin can be dangerous, for example causing a pressure necrosis crater. The only evidence of this was presented with respect to the MammoSite device, not the Contura, thus the court cannot say that the evidence presented thus far supports Hologic's contention that the presence of Contura in the market presents anything but a speculative harm. SenoRx, however, should be careful not to promote the Contura with unauthorized or unproven claims.

Absent evidence that the Contura is causing public harm, there is a public interest in expanding the treatment possibilities for breast and other cancers. [redacted] and, based on this evidence appears to be a realistic treatment option. Gearhart Decl. ¶ 11. Therefore, the public interest factor tips in SenoRx's favor.

4. Balance of Hardships

Final factor is the balance of harms. On the one hand, Hologic contends that its substantial investment of over [redacted] will be irreparably damaged and that its credibility with customers will be damaged. [redacted]

Although Hologic argues that SenoRx's core product market is in breast diagnostic equipment and that an injunction would merely keep the status quo by restricting SenoRx to its prior market focus, this does not eliminate SenoRx's investment in commercializing Contura.

(b) Dissemination of information on drugs or devices not evidence of intended use

Notwithstanding subsection (a), (f), or (o) of section 352 of this title, or any other provision of law, the dissemination of information relating to a new use of a drug or device, in accordance with section 360aaa of this title, shall not be construed by the Secretary as evidence of a new intended use of the drug or device that is different from the intended use of the drug or device set forth in the official labeling of the drug or device.

Such dissemination shall not be considered by the Secretary as labeling, adulteration, or misbranding of the drug or device.

The hardships asserted by each party are similar: lost investments, loss of sales, loss of market share, loss of credibility with customers. This factor does not favor either party. As the court discussed previously, the harm to Hologic could be compensated economically. Further, the parties have represented to the court that they would be able to proceed to trial in 60 to 90 days. To the extent that Hologic may suffer harm to its reputation or that the price erosion affecting reimbursement rates Hologic predicts will come to pass, it is unlikely that it will happen in that short duration. By contrast, a 60 to 90 day injunction would scuttle the launch of Contura at the height of SenoRx's plans. [redacted]. As the court determined above, it appears that Hologic waited until it would be most harmful to SenoRx to seek this injunction. Such a tactical delay, in addition to tending to weigh against a finding of irreparable harm to Hologic, also provides support that SenoRx would suffer a greater harm by an injunction than Hologic would suffer should the requested injunction be denied.

III. ORDER

For the foregoing reasons, Hologic's motion for preliminary injunction is denied. The parties shall contact the court's Courtroom Deputy at (408) 535-5375 to schedule a trial 60-90 days from the date of this order.

DATED: 4/25/08

Ronald M. Whyte
RONALD M. WHYTE
United States District Judge

United States District Court
For the Northern District of California

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Dated: 4/25/08

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Chambers of Judge Whyte

United States District Court
For the Northern District of California